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10/723,486

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Kenneth F. DeFreitas

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06/25/2009

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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT

PAPER NUMBER

3768

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/723,486	<b>Applicant(s)</b> DEFREITAS ET AL.	
	<b>Examiner</b> ELLSWORTH WEATHERBY	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-122 is/are pending in the application.
- 4a) Of the above claim(s) 1-56 and 101-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/18/2008</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species.

I. Claims 1-57 & 101-122

II. Claims 57-100

2. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record. Species I is drawn to the positioning of the breast with particular structures to acquire mammographic x-rays using a movable detector, which would generally require a search in 378/37. Species II is directed toward acquiring image data of the patient's breast from particular viewpoints and subsequently processing the data to produce particular 2D views and particular 3D views for display.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

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not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. During a telephone conversation with Lindsay McGuinness (Reg. No. 38549) on 6/10/2009 a provisional election was made without traverse to prosecute claims 57-100. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-56 and 101-122 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 58, 65, 69, 71-72, 77, 80, 85-87 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 58 and 80, applicant claims, "a patient x-ray dose comparable to that used in conventional mammography but the image data for each of the tomosynthesis positions are taken at a substantially lower dose.". The Examiner stands that a patient x-ray dose comparable to that used in conventional mammography is undefined. Here, a dose comparable to that used in conventional mammography could be construed as any or all of; a subjective estimate, a narrow range of doses or a wide range of doses. This applies

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*Mutatis mutandis* to claims 69 and 91. Regarding claims 65 and 87, "Applicant claims the source at said mammogram position is at an angle of substantially 0° relative to the breast.". Here, it is not clear to which axis or view of the breast the angle of the source is being related. Regarding claim 71, Applicant claims a kVp range. However, only a starting substantially higher than 25kVp limit is claimed to describe the range. Furthermore, the implications of the limitation "substantially higher" are not clear. This applies *Mutatis mutandis* to claim 72. Regarding claims 85-86, it is not clear whether or not "the mammogram" refers to the mammogram position or mammogram image.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 57-68, 73, 79-92, 95 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhard et al. (USPN 6,751,285) in view of Tang et al. (Pub. No.: 2003/0026386).

Eberhard et al. '285 (hereinafter Eberhard) teaches a method of imaging a patient's breast with x-rays using a flat panel digital x-ray imager to obtain both two dimensional image data for a conventional mammogram data and three-dimensional (3D) image data for tomosynthesis images in a single breast compression, using an

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anti-scatter grid in obtaining some but not all the image data, comprising: immobilizing a patient's breast between an x-ray source and a flat panel digital x-ray imager (col. 3, l. 65-col. 4, l. 9); energizing the x-ray source to emit x-rays at each of a plurality of different angular positions of the source relative to the breast while the breast remains immobilized, and concurrently using the imager to derive x-ray projection image data for the respective positions (col. 4, ll. 2-19); wherein the image data for at least one of said positions, called hereafter a mammogram position, are taken at a view matching that of a conventional CC and/or MLO view used in conventional mammography, and the image data for a plurality of other positions, called hereafter tomosynthesis positions, are taken at other relative angles of the source and breast (fig. 1; col. 2, l. 48- col. 4, l. 9: Here image data may be acquired in any order); optionally using an anti-scatter grid between the patient's breast and the imager for at least the mammogram positions and optionally not using the grid for at least some of the tomosynthesis positions (col. 6, ll. 9-18); and processing the image data taken for the mammogram position to form and display a mammogram and using the image data taken for said tomosynthesis positions to form and display tomosynthesis images of the breast (col. 3, l. 7, l. 64; claim 16).

Eberhard also teaches acquiring the images at a plurality of doses in accordance with the thickness such that a mammogram can be acquired at a given radiation dose and each image of the tomogram can be acquired at a lower dose (col. 4, l. 47-col. 5, l. 60).

Eberhard also teaches energizing the x-ray source at different angular positions comprises energizing the source intermittently during a continuous movement thereof relative to the breast covering at least some said positions (col. 6, l. 65- col. 7, l. 17).

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Eberhard further teaches energizing the source while stationary relative to the breast for at least one of said positions (col. 7, ll. 18-47).

Eberhard teaches all the limitations of the claimed invention except for expressly teaching using an anti-scatter grid between the patient's breast and the imager for at least the mammogram positions but not for at least some of the tomosynthesis positions. Eberhard also does not teach that acquiring x-rays at a kVp range substantially higher than 25kVp

In the same field of endeavor, Tang et al. '836 teaches anti-scatter grids and collimator designs in imaging and mammography at 35kVp (abstract; 0010; 0098). Tang goes on, teaching methods for imaging while moving the anti-scatter grid, such that the anti-scatter grid is used for at least the mammogram positions but not for at least some of the tomosynthesis positions [0113-0128; 0218-0240].

Because Eberhard teaches optionally using an anti-scatter grid, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mammography system of Eberhard in view of the system or method of using the an anti-scatter grid in x-ray mammography Tang. The motivation to modify Eberhard in view of Tang would have been to avoid grid shadows, as taught by Tang [0005].

8. Claims 70, 72 and 93-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhard et al. (USPN 6,751,285) in view of Tang et al. (Pub. No.: 2003/0026386) as applied to claims 57 and 94 above, and further in view of Karellas et al. (Pub. No.: 2003/0169847).



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9. The mammography system of Eberhard in view of Tang teaches all the limitations of the claimed invention except for expressly teaching using a Tungsten target. Eberhard in view of Tang also do not expressly teach that at least some of the image data re acquired with x-ray in a range up to 50 kVp.

10. In a related field of endeavor, Karellas et al. '847 teaches x-ray imaging (abstract). Karellas goes on, teaching the use of a Tungsten target [0149; 0209]. Karellas also teaches acquiring image data in a range near 50kVp [0088; 0280].

11. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify mammography system of Eberhard in view of Tang with the Tungsten target of Karellas. The motivation to modify Eberhard in view of Tang with Karellas would have been to utilize any of the known target, including the high power tungsten target of Karellas.

12. Claims 74-75 and 96-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhard et al. (USPN 6,751,285) in view of Tang et al. (Pub. No.: 2003/0026386) as applied to claims 57 and 79 above, and further in view of Tumey et al. (USPN 5,941,832).

13. The mammography system of Eberhard in view of Tang teaches all the limitations of the claimed invention except for expressly teaching displaying the mammogram and tomosynthesis images for concurrent viewing.

14. In a related field of endeavor, Tumey et al. '832 (hereinafter Tumey) teaches computer digitization of mammogram image data (abstract). Tumey goes on, teaching

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the use of concurrent display of multiple mammography image data (col. 3, l. 51- col. 4, l. 2).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mammography system of Eberhard in view Tang with the concurrent display of Tumey. The motivation to modify Eberhard in view Tang with Tumey would have been to provide efficient display of the datasets using known display means.

16. Claims 76 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhard et al. (USPN 6,751,285) in view of Tang et al. (Pub. No.: 2003/0026386) as applied to claims 57 and 79 above, and further in view of Wang et al. (Pub. No.: 2003/0212327).

17. The mammography system of Eberhard in view of Tang teaches all the limitations of the claimed invention except for expressly teaching that the mammogram and tomosynthesis images on adjacent screens.

18. In a related field of endeavor, Wang et al. (hereinafter Wang) teaches an adjunctive mammography system comprising an adjunctive display configured for quick, intuitive, interactive viewing of data derived from volumetric ultrasound scans, the data being displayed near a conventional x-ray mammogram display (abstract). Wang goes on, teaching the use of a plurality of adjacent screens, displaying mammogram and 3D image data [Fig. 1; claim 25].

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19. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mammography system of Eberhard in view Tang with the displays of Wang. The motivation to modify Eberhard in view Tang with Wang would have been to provide efficient display of the datasets using known display means, as taught by Wang [abstract].

20. Claims 78 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhard et al. (USPN 6,751,285) in view of Tang et al. (Pub. No.: 2003/0026386) as applied to claims 57 and 79 above, and further in view of Hseih et al. (USPN 6,574,304).

21. The mammography system of Eberhard in view of Tang teaches all the limitations of the claimed invention except for expressly teaching that the tomosynthesis images represent thick slices of the breast, about 5 to about 10 mm thick.

22. In a related field of endeavor, Hseih et al. (hereinafter Hseih) teaches computer aided acquisition and display of medical images (abstract). Hseih goes on, teaching the acquisition of thick slice images about 5 to 10mm thick (col. 5, ll. 16-34).

23. Because Eberhard teaches variable thickness images, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the mammography system of Eberhard in view Tang with the thick slice images of Hseih. The motivation to modify Eberhard in view Tang with Hseih would have been to acquire images of any thickness, as desired by an interventionalist, including the known 5-10mm slice thickness of Hseih.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768